Title: ***Innovative medicines in the portuguese private health sector: a strategic vision***

Field of study: Strategy

Purpose: Dissertation for obtaining the Degree of Master in Business Administration
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Abstract

The present dissertation aims at contributing to a strategic view over the use of innovative medicines in the portuguese private health sector, as a way of being complementary to public system that nowadays finances most of the innovative medicines.

With the rationalization of expenses in the public health sector, pharmaceutical companies tend to look for opportunities of expansion to the private sector.

The creation of innovative financial models for the private sector to cover innovative treatments is the proposed way of surpassing the restriction on the NHS sales of innovative medicines.

This can be both for differentiating private health providers from the NHS or for the creation of premium services that can be differentiated from other private providers of the portuguese market.

Acknowledge

The present dissertation wouldn't be possible without the sponsorship of Novartis. I would like to thank Cristina Campos for entrusting in us the so challenging strategic project *Unlocking the private sector* for innovative medicines, to Rita Serôdio because of her dedication and guidance throughout the project, and to all Novartis people that shared their knowledge with us.

A note of thankfulness to the interviewees of the private health sector that shared their vision of the Portuguese healthcare system with us.

I acknowledge my gratitude for Prof. Celine Abecassis-Moedas who was able to guide us trough the challenges of the Consulting Lab project.

My greatest gratitude goes also to the Lisbon MBA International as an institution and to their members of staff, professors and directors, and surely to my 2012 colleagues of class.

I remark the gratefulness to my Family.

Last but not the least, I would like to thank my group of colleagues Cláudia Amaro, Rawan Kanj and José Pereira for the learning I took from them during the Consulting Lab.

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Acronym List

•ACSS Administração Central do Sistema de Saúde

•ADM Assistência na Doença aos Militares das Forças Armadas

•ADSE Assistência na Doença aos Servidores Civis do Estado

•APHP Associação Portuguesa de Hospitalização Privada

•CNECV Conselho Nacional de Ética para as Ciências da Vida

•DGS Direcção Geral da Saúde

•DRG Diagnosis Related group

•EMA European Marketing Authorization

•ERS Entidade Reguladora da Saúde

•ESS Espírito Santo Saúde

•EU European Union

•FDA American Food and Drug Administration

•GDP Gross Domestic Product

•HPP Hospitais Privados de Portugal

•INE Instituto Nacional de Estatística

•IMI Inovative Medicine Initiative

•Infarmed - Autoridade Nacional do Medicamento e Produtos de Saúde

•JMS José de Mello Saúde

•MA Marketing Authorization

•MCDT Meios Complementares de Diagnóstico e Terapêutica

•MoU Troika Memorandum of Understanding

•NHS Portuguese National Health System

•OECD Organization for Economic Cooperation and Development

•OOP Out of Pocket

•PPP Public Private Partnership

•PT-ACS Portugal Telecom - Associação de Cuidados de Saúde

•SAD Serviço de Assistência na Doença PSP GNR

•SAMS Serviço de Assistência Médico-Social Bancários

•SIGIC Sistema Integrado de Gestão de Inscritos para Cirurgia

•SPC Supplementary Protection Certificate

1. Intoduction

Management problem

Within the portuguese health context, is the introduction of innovative medicines strategic to the private health providers?

Or, more specifically:

Within the portuguese health context, can the private health sector absorb/finance the uncaptured pool of patients in need for innovative medicines?

Relevance of the management problem for business organizations

The management problem above described is relevant for the business organizations of the portuguese private health sector: the private health providers, private health financers (health insurances, private subsystems) and it's of major importance to the pharmaceuticals with innovative medicines patents.

This problem can also affect the performance of the other players of the health systems, namely the NHS (Portuguese National Health System) and the public subsystems. If put in practice may also call the attention of health regulators.

The private sector creates values either trough complementary or alternative services to the NHS.

Expenses with medicines represented in 2010 24% of the total health expense: 17.300M € (OECD, 2012). Innovative medicines due to their usual high cost, have been contributing to an increase on the healthcare expenses. Oncologic + Rheumatoid Arthritis + HIV AIDS medicines represented 2,71% (469M €) of total health expenses in 2010 (Infarmed, 2012).

Parmaceutical companies observe that not all the patients with a specific disease are being treated: there is an uncaptured pool of patient and therefore an uncaptured potential. These patients could be in part captured by the private health system, if a strategy to finance them existed.

The question in analysis arises from the project developed on the Consulting Lab: *Unlocking the private sector*, for innovative drugs of Novartis pharmaceutical. The project was developed having as sponsor the pharmaceutical company Novartis Portugal.

The relevance of the problem for the understanding of management

The question: Within the portuguese health context, is the introduction of innovative medicines strategic to the private health providers? is a question about entering a new market with products that are the most innovative of the pharmaceutical industry, usually they're also the most expensive and, it could be said, the most premium.

An analysis of innovation management through the entrance of innovative products in new markets is the paradigm analysed.

2. Literature review

(a) Review of conceptual frameworks

(a 1) Entering a new market with innovative products

In this work project it's analyzed the entrance of pharmaceutical companies with innovative medicines into the portuguese private health market.

Five forces model

From the five forces model of Michael Porter is possible to analyze the threat of new entrants, threat of substitute products or services, bargaining power of buyers, bargaining power of suppliers and rivalry among existing firms.

The threat of new entrants in the private market is high if these new entrants are the established innovative pharmaceutical companies already with sales on the public system.

The substitutes can be other innovative products, technology or treatments that can be a choice for the private providers to differentiate themselves. But the joint provision of the latest technology, of innovative products (from several innovative pharmaceutical companies), as well as of more effective treatments, can finally leverage all together the providers differentiation.

The bargaining power of the buyers of innovative medicines (centralized procurement centers by health group) depends on the patient pool they might be able to attract, in that case a price reduction might happen due to economies of scale.

The rivalry among existing firms is not usual for innovative medicines once there is usually only one product to treat, prevent or cure that disease. Actually many times two companies share the ownership of the same innovative product (because of the expensive cost of development). However competition may arise from off label products, or from less expensive medicines for different medical conditions (preventions, treatment, cure) – eg. acute asthma patients can punctually control an asthma attack with a cheap medicines but they could prevent it with a innovative but much more expensive medicine.

Innovation as a creative destruction

Pharmaceutical companies with truly innovative medicines seem to be the unlocking of a new market: the private health market. They already have on their product portfolio innovative medicines that are so disruptive that destroy other established firms competencies or complementary assets - *creative destruction* concept (Schumpeter, 1950). These companies products or treatments became obsoletes when compared with the truly innovative drugs. The process of entering the private market with effective innovative drugs is therefore an *Architectural Innovation* in the Abernathy and Clark adapted model, 1985.

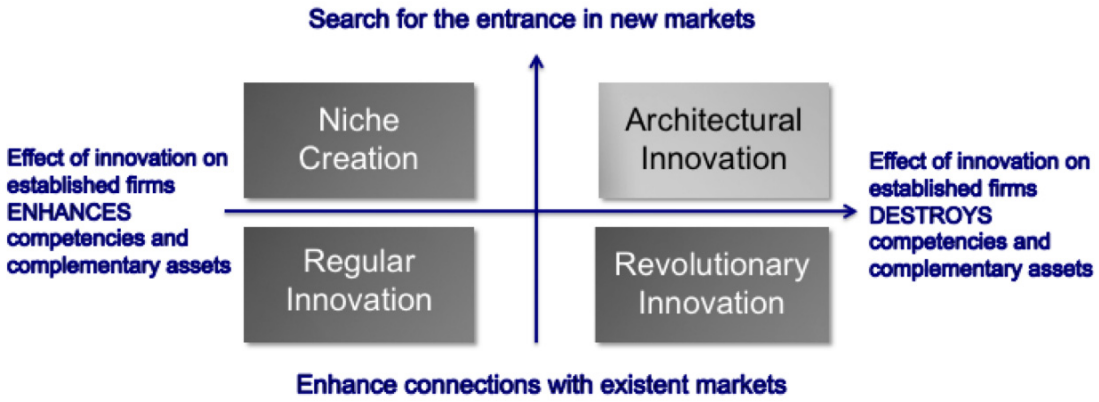

Fig.1. Types of innovation: effect on established firms and ability to capture a new market

Source: Adaptation from Abernathy and Clark, 1985 and Dantas and Moreira, 2011.

Innovative medicines that bring major benefits highly influence the patients (consumers) lives. Once again, these drugs disruptiveness may make obsolete established firms solutions to treat, prevent or cure a specific diseases. These truly innovative medicines are *Strategic Innovation* assets, they're key success products that enhance the possibility of entering and dominating a new market.

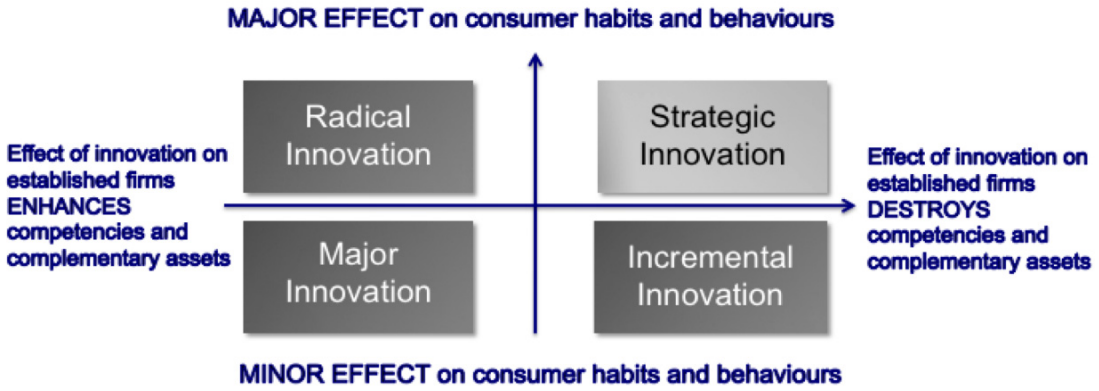

Fig.2. Types of innovation: effect on established firms and on consumers

Source: Adaptation from Markides and Geroski, 2004.

Truly innovative medicines are so disruptive, they're *new to the world* and involved at a *system level*, they're therefore breakthroughs for the pharmaceutical sciences and to the world. Being the intellectual property legally protected their strategic advantage is protected for the time the patent is protected, what makes the owner of that compound a monopoly owner if there is no other medicine to be prescribed for the same disease.

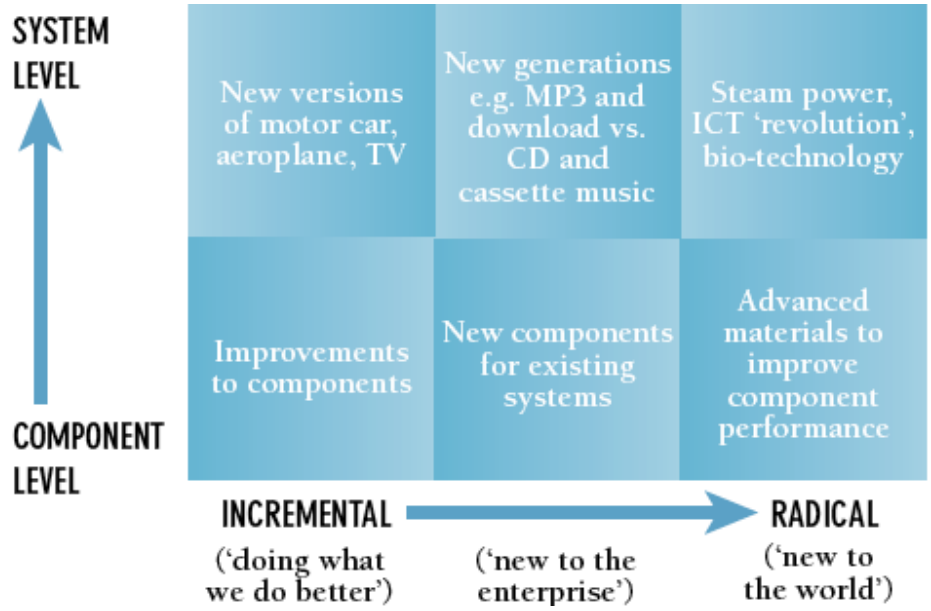

Fig.3. Dimensions of innovation and its examples

Source: Tidd, Joe et al., 2005

New market - new positioning

The entrance on the new market: the private market is most probably to be done trough financing institutions due to the usual high costs of innovative medicine. The health insurances would play a role associated with the private providers that supply the care to patients. A new positioning should be considered for health insurances to *target* portuguese aware of the health risks they might face and of the probable rationalization of the public health system. *The point of difference* would be the availability and the reimbursement of not only innovative medicines, but also innovative treatments and the latest technology. *The reason to believe* of those innovative treatments would be the European Marketing Authorization (no need of the Infarmed approval for reimbursement) and the *additional clinical efficacy and/or effectiveness* when compared with the current care (Lievens, 2010).

Consequently, innovation would be more than only on the side of a *product innovation,* but also, on the side of the *position innovation* if entering a new market. Both together can initiate what could be a *paradigm of innovation* - 4 P's of Innovation (Tidd, Joe et al., 2005).

The concept of *market position,* introduced by Francis and Bessans (2005), concerns especially the introduction of a *established product/service* on a *new context;*

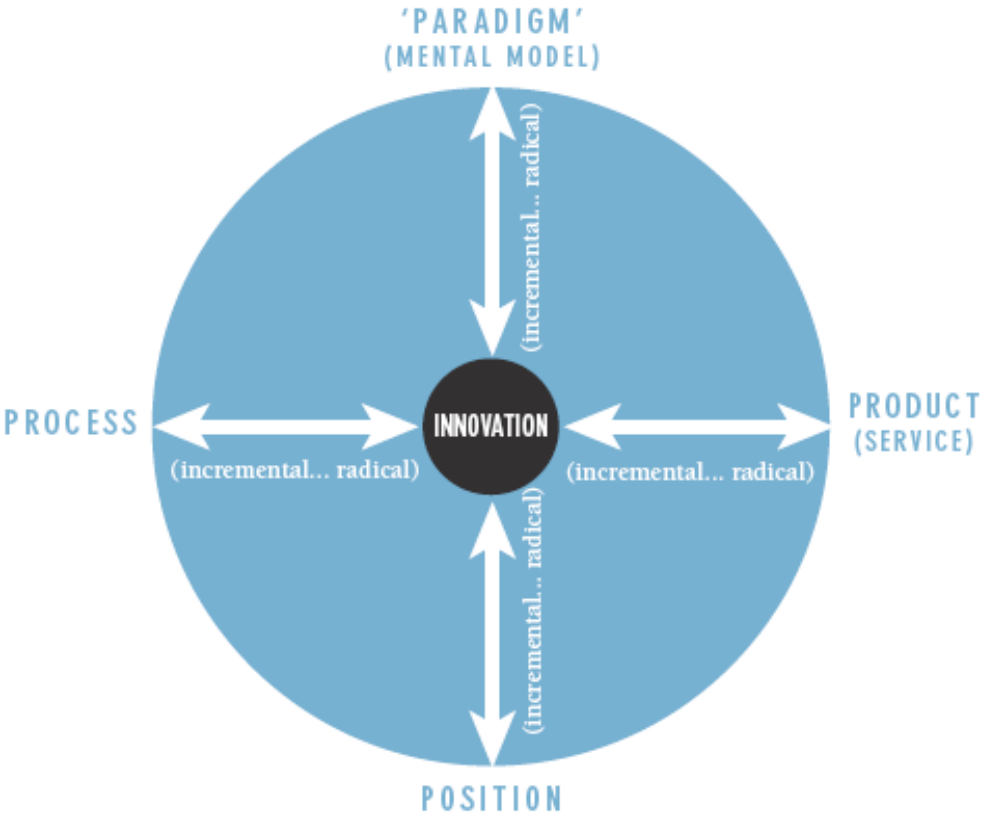

Fig.4. Innovation space (4 P's of Innovation)

Source: Tidd, Joe et al., 2005

Blue Ocean Strategy

Kim and Maubourgne (2005) present a reflection about how a *Blue Ocean Strategy* can be created. The entrance of innovative medicines in the private health sector can open a window to capture patients that are not nowadays receiving innovative treatments on the public sector for several reasons. The latest medical devices technology is being introduced in private providers as a way of differentiation, some of this technology is only existent on private sector what attracts the best doctors once they want to work with the latest technology. The introduction of innovative medicines should happen in partnership with the financing groups, since the target medicines are very expensive. An investment on patient education might be made announcing the benefits and effectiveness of those new drugs. Some patient pool might be uncaptured because few diagnosis were made, investment in rare diseases diagnosis might therefore be financed by pharmaceutical companies.

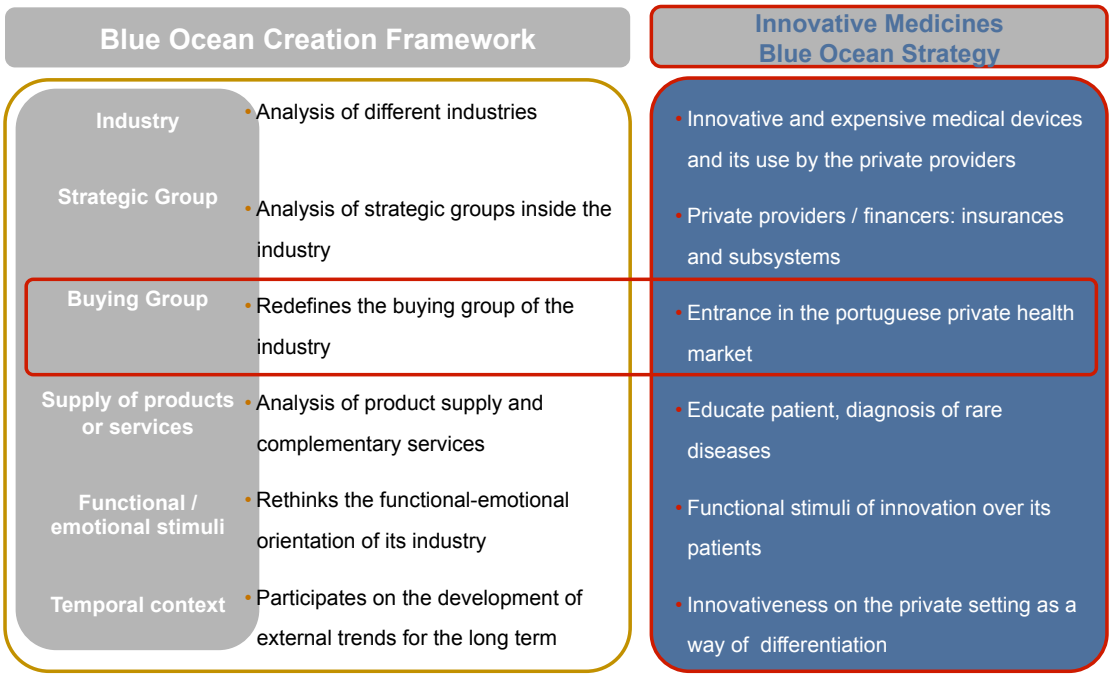

Fig.5. Blue Ocean Strategy for innovative medicines in the portuguese private health sector

Source: Adaptation from Kim and Maubourgne, 2005.

In Resume

In the analysis of the problem of capturing patient pool for innovative medicines the entrance on the private health market is to be the trigger point. A source of *radical innovation* development as the innovative medicines are, enables a competition *against the existing* market (mostly the public health market), but, furthermore, a *significant market change/disruption* against *non-consumption* creates a *complete new market*, (Tidd, Joe et al., 2005 and Christensen and Raynor, 2003).

(a 2) Innovative medicines

The concept of innovative medicines is usually associated with higher cost of care. Long term calculations are then done to analyse the savings that can be made either for prevention, treatment /stabilization or cure of a disease, but still the vast majority lead to an increase in expenses. Therefore innovative medicines when compared with the existing care (if there is one), have a cost premium. But premium benefits might also come from the use of these medicines.

The quality of pharmaceutical innovation varies widely. It ranges from breakthrough treatments - for life threatening diseases to minor modifications of medicines that have been on the market for some time.

Valuable innovative medicines are both truly innovative and valuable. A drug can be called truly innovative if and only if it offers additional clinical efficacy and/or effectiveness as compared to

current care (Lieven, 2010). *If, in addition these medicines fill an unmet medical need we propose to call them valuable (http://ec.europe.eu/pharmaforum/).*

Important delays in market access to innovative medicines *are observed* (IMS Health, 2010). Time to access market is valuable to pharmaceutical companies due to patent expiration over time. Pricing and reimbursement decisions arise then, the magnitude of innovation should be measured through transparent and rational method.

Before a new medicine becomes available to patients it will have gone through a long process of research, registration and market introduction. On average there is a 12 year period between the discovery of a new active compound and the availability of a respective medicine to patients. In estimated numbers preclinical research takes 4 years and 25,2% of the total R&D investment, clinical trials take 6 years and 58,6% of R&D, and the registration and reimbursement procedures take another 2 years and 16,2% of R&D value. The remaining patent period is then of 8 years, after which a supplementary protection certificate (SPC) may be granted for a maximum of 5 years (Nefarma, 2011 and PwC, 2013). The period of time that elapses between the filing for an application for a patent for a new medicine and its marketing authorization (MA) may make the period of effective protection under the patent rules insufficient to cover the investment put into research (Lieven, 2010).

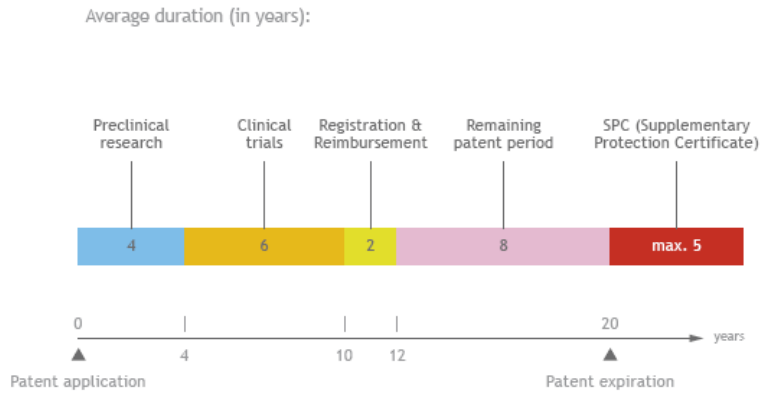

Fig.6. Development and patent period of a medicine. Average duration.

Source: Nefarma. 2011: AGIM, Recherche et Vie.

There should be a clear definition of areas in the health care where there are unmet medical needs. However it's known that the creation of new scientific knowledge usually depends on *serendipity, pure luck or other factors that are difficult to steer*, and not on demand pulled approach.

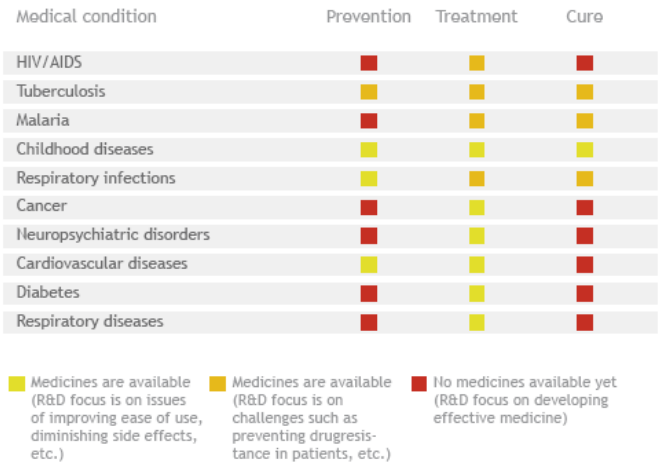

Fig.7. Status of medicine development of various conditions.

Source: Nefarma, 2011: IFPMA, 2008.

The Innovative Medicines Initiative (IMI) focuses on five disease areas that are considered of unmet need, neglected need or rare diseases: cancer, brain disorders, infectious diseases, inflammatory diseases, diabetes and other metabolic diseases (IMI, 2006).

Economics

There should be distinguished several levels of innovation, regardless of the economic costs.

Returns on health investments should be calculated including the patient well-being and the economic competitiveness. On a health economic analysis a comparative evaluation of at least two alternative medical interventions is made with both the costs and the health benefits/effects. The current therapy might also be a no action option (Drummond, 2008), if there is no actual treatment, cure, or preventive one. Variables as need, value for money and relative effectiveness could play a role in pricing and reimbursement decision, however nowadays criteria for MA remain to be safety, quality and efficacy.

(a 3) Complementary versus alternative service

As it has been said the private sector creates value either trough complementary or trough alternative services to the NHS. To position innovative medicines in the private market an analysis should be made over the level of complementariness or alternation of the systems in what concerns truly innovative drugs.

An alternative service is a service that may substitute the other.

In the healthcare system when care is provided both by the public and private sector, patient may opt to choose one or the other. In the portuguese health system were public care is a universal right the private sector might be considered duplicative (Barros and Siciliani, 2011).

A complementary service offers care that is not covered by the other.

In the health system, care that is not covered by the public can potentially be covered by the private sector. The *interface* between public and private is different: in this case private sector complements the public.

Private providers can also be complementary or alternative one to the others.

The provider offers the service, and it can be reimbursed by the private insurance, by the subsystem or paid directly by OOP or even by the state.

Colombo and Tapay (2004) distinguish the concepts of duplicative, complementary and supplementary for private insurance providers. The supplementary role of insurance is related to the coverage of co-payments of public system.

In Portugal nowadays patients may decide whether to go to public providers, paying the respective co-payment (might be equal to 0), or in the case they have insurance or subsystem go to the private paying a value for the co-payment.

The variables that influence patients choice are the price, the *clinical quality*, the benefit from becoming healthier, *level of amenities*, waiting time and *individual household net income* (Barros and Siciliani, 2011). Innovative medicines enter as a variable that influences *clinical quality*. Different funding systems have different budget possibilities. Nowadays public system has limited budgets, it aims to provide care that has the *highest benefits* or better to be said, the better *benefit cost ratio* for the politically allocated budget (Barros and Siciliani, 2011).

(a 4) Why do patients choose the private health sector

Barros and Siciliani in 2011 intuitively consider that the variables that make the patient choose between different health systems are the amenities, waiting times and clinical quality. Some other variable could be include, for instance the co-payments values or the distance to the health unit. The public and private systems have differences in terms of what they have best. The private health sector tends to be alternative or complementary to the public. In Portugal its usually considered that public hospitals have higher quality than the private – mostly because of its ability to have economies of scope and scale (Barros and Siciliani, 2011), but higher waiting times (Sistema Integrado de Gestão de Inscritos para Cirurgia - SIGIC) and less amenities than the private. It's important to note that in Portugal doctors are able to practice medicine both on public and private sector at the same time, exclusivity is elective. Some diseases are only treated by the public sector and others by the private sector, the case of haematology for the public hospitals and haemodialysis (CEGEA, 2007), dental care or eye care for the private sector.

From Costa and Garcia study based in Catalonia (2003) evidence suggests than a decrease on the perceived quality in public system generates higher private health number of beneficiaries.

From the interview with Multicare it was possible to learn that nowadays the public copayments are so high that private insurance plans have usually lower co-payments. Patients therefore weight constantly all the choosing variables to decide either to go to the private or public system.

In case of cancer treatments or emergency care waiting times can be zero or low in the public system (Barros and Siciliani, 2011), in that case the only variable that usually affects the choice is the difference in amenities.

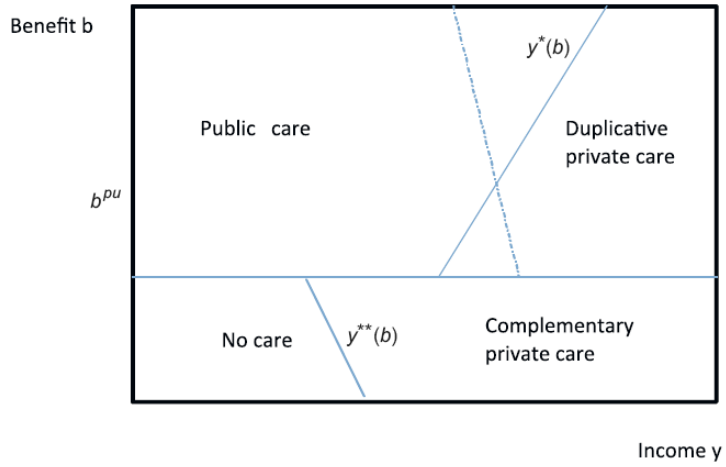

Fig.8. Choice between public and private care. Public and Private sector interface.
Bigger attractiveness – higher patient pool.
Source: Barros and Siciliani, 2011.

If the public care is very inclusive the private sector can only exist on a duplicative or alternative way. Whilst if the public sector provides no care for a specific disease there is much more scope for the complementary existence of the private sector.

Certainly the presented framework is to be extended to the insurance providers. Patients can opt to pay a health insurance premium if they want to be covered by a private health insurance.

As there might be a reduction on innovative medicines prescription in the public sector, there might be a window for private sector to complement the offer of these medicines. However *innovative therapies will require innovative financing* models (Portuguese EU Presidency, 2007). Private insurance companies will have an important influence on the emergence of these new financial models. The past years trend of increasing the caps of coverage of insurance plans as a way of including more expensive/low probability diseases may be one of these innovative models. Another innovative financial model could arise from the partnership of pharmaceutical and insurance companies for the same differentiating objective. To acknowledge *unmet medical needs,* to *improve medication adherence and clinical outcomes* US insurance companies have demonstrated interest to partner with pharmaceutical companies (Health Research Institute, 2012).

(b) Review of pre-existing attempts to shed light on the problem

The problem in analysis has been more latent over the late years once more innovative and expensive drugs have been found, contributing to an escalation of medicine costs.

The actual economic crisis accentuates the need of rationalization on the public sector in Portugal and the recent entrance of Troika in April 2010 and its Memorandum of Understand (MOU) puts in place cuts in healthcare costs that affect directly medicines.

On their 2006 study Lafuna, and Tilluel analysed Geramny, UK, France and Spain on the management of innovative medicines. In the Netherlands a list of ten very expensive medicines was identified in 2002, and they begun to be reimbursed by the Sickness Fund. Critics aroused once the list was based on price and not on cost/benefit ratio. This is a major concern in France where reimbursement of expensive indications by the French Sickness Fund pushed up dramatically the sales of the respective medicines.

How to manage innovative and expensive medicines was identified as a concern throughout the four countries studied, mainly in general hospitals with cancer services. In this case a annual increase in medicine budgets was from 10% to 25%.

In these hospitals campaigns as direct to consumer advertising (DTC) or specific formularies for very costly medicines are used to inform patients. It's common to exist negotiation of the management of these medications with the hospital physicians and moreover with third party payers for extra budgets.

The pharmacists of the general hospitals in Germany tended to consider the problem of innovative and expensive medicines in German hospitals of little concern. *The first reason was that the drug budget(…)* for *innovative and costly compounds (…) represented less than 5% of the hospital's total budget (Lafuna, and Tilluel, 2006).*

(c) Macro and micro environment analysis: innovative medicines in the portuguese health system

(c 1) Health expenses and care distribution: public and private

The healthcare system is formed by two systems that coexist in the country: the public and the private systems. In 2010 10.7% of GDP was spent on health expenditure corresponding to 17,5 B€ (and 9,8 % of GDP in 2011). Public funding was of 67,3 % of total health expenditure in 2010 with the NHS representing 56,8% of the same total. Private funding is increasing, and was 32,7% of total health expenditure in 2010. The private financing is mainly in the form of OOP payments (co-payments and direct payments by the patient).

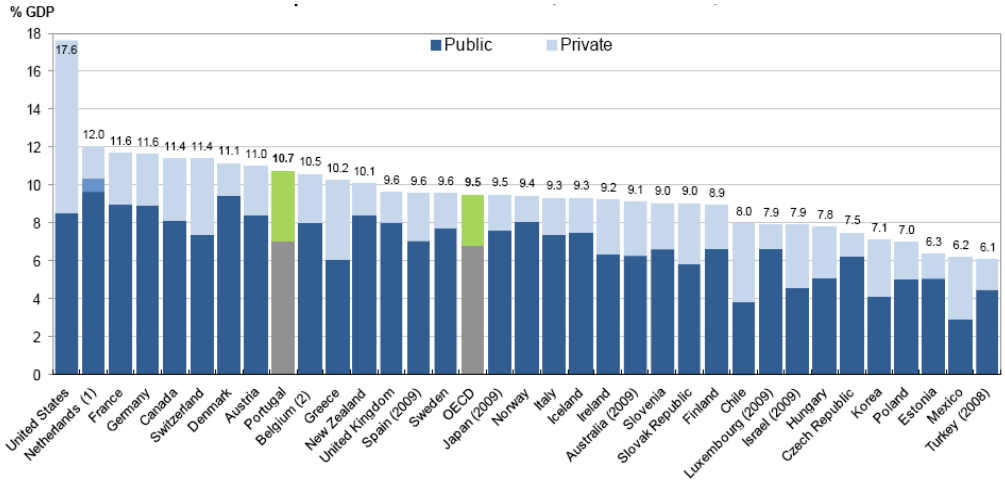

Fig.9. Health expenditure as a share of GDP, OECD countries, 2010.

Source: OECD, 2012.

Funding mix for the health system, 2005-2010	2005	2006	2007	2008	2009	2010
TOTAL HEALTH EXPENDITURE ('000 €)	*15,110,504*	*15,109,448*	*15,838,602*	*16,602,767*	*17,256,221*	*17,534,675*
	100%	*100%*	*100%*	*100%*	*100%*	*100%*
PUBLIC SECTOR	**69.8%**	**67.8%**	**67.6%**	**66.1%**	**67.6%**	**67.3%**
General government excluding social security	68.7%	66.7%	66.5%	64.8%	66.2%	66.0%
National Health Service	55.7%	53.6%	53.2%	51.8%	53.0%	56.8%
Public health subsystems	6.8%	6.8%	7.4%	7.0%	7.4%	4.0%
Other public institutions (other than social security funds)	6.3%	6.3%	5.8%	6.0%	5.9%	5.2%
Social security funds	1.1%	1.2%	1.2%	1.3%	1.4%	1.3%
PRIVATE SECTOR	**30.2%**	**32.2%**	**32.4%**	**33.9%**	**32.4%**	**32.7%**
Private health subsystems	2.4%	2.4%	2.2%	2.2%	1.9%	1.8%
Private insurance	2.0%	2.4%	2.5%	2.7%	2.7%	2.8%
Private Out-Of-Pocket payments	25.2%	26.8%	27.2%	28.5%	27.3%	27.5%
Non-profit organisations	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Corporations (other than health insurance)	0.4%	0.4%	0.4%	0.5%	0.5%	0.5%

Fig.10. Funding mix for the health system, 2005-2010.

Source: INE, 2012.

In terms of distribution of provided care 40% of the healthcare service was provided by the private sector. Private health expenditure was mostly concentrated in Dentistry, Ultrasound Scans, Clinical Analysis and Specialty Consultation.

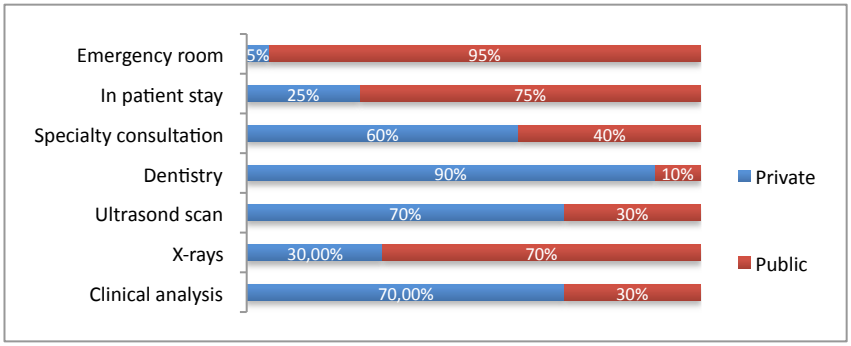

Fig.11. Public and private funding divided by service.

Source: APHP, 2010.

(c 2) Private Providers

The private sector is composed by the private providers, that are financed by private insurances, private subsystems, public subsystems, OOP payments, or by the state (in case the NHS doesn't has enough resources).

The four major private providers represent 70% of market share, generating turnover of 924M € in 2011 corresponding to a 13% growth from 2010. The private providers sector is consolidating more than growing, new branded hospitals and clinics dry up existing small players.

The major player is José de Mello Saúde - JMS (404M €), followed by Espírito Santo Saúde – ESS (270M €) and Hospitais Privados de Portugal - HPP (190M €), with a smaller share, but still very representative there is the Trofa Saúde group (60M €) – values of 2011.

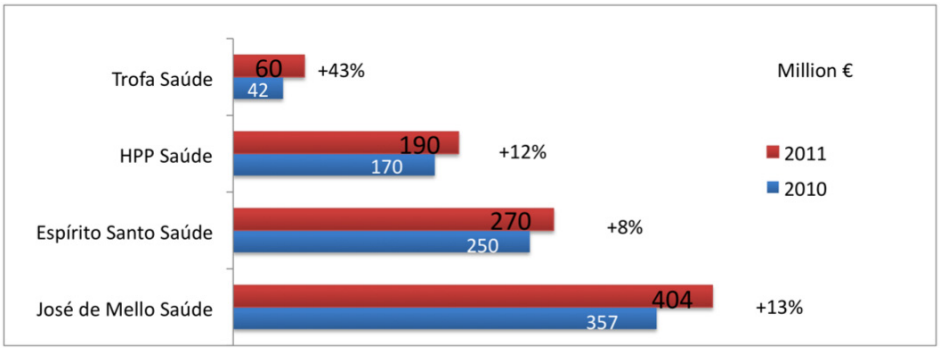

Fig.12. Private Providers.

Source: APHP, 2012.

Build, operated and maintained by the private providers but serving the NHS patients there are the Public Private Partnerships (PPP). The Loures Hospital – ESS, the Cascais Hospital - HPP, the Braga Hospital – JMS and the Vila Franca de Xira Hospital - JMS. Currently PPP's are struggling to break even due to effective risk sharing, to the financing model and to the unfinished restructuring of the hospital map.

(c 3) Private insurances

Roughly 20% of the population (2,15 M) has some form of Voluntary Health Insurance (VHI), 36% are individual insurance plans; the remainder 64% are corporate plans. Health insurance market has been growing but decelerating in 2011. In terms of volume, the market grew 1,5% in 2011 (compared to 7,0% in 2010). Multicare is the market leader, with 600.000 customers in end of 2010, Multicare counts with 16.000 providers, of which 70 hospitals.

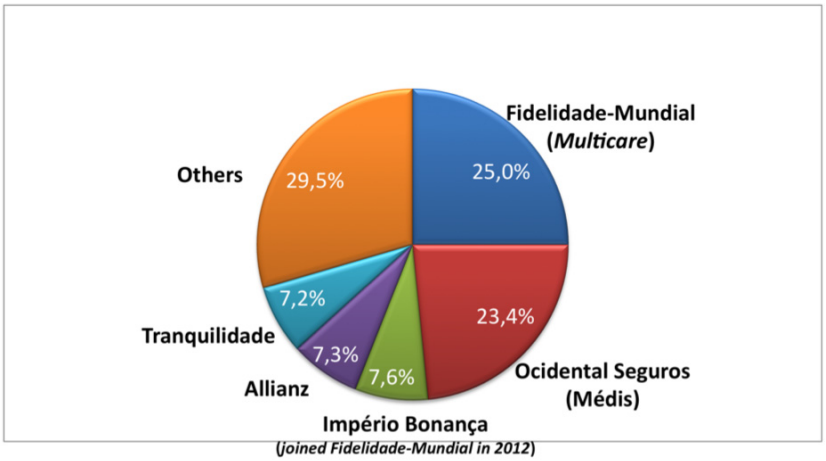

Fig.13. Health insurance providers market share.

Source: Associação Portuguesa de Seguradores, 2012.

As per *Associação Portuguesa de Seguradores*, such growth has been fuelled by the growing limitations of the NHS, the increased confidence in the insurance industry, its relatively accessible cost, and the convenience and easy access to health care they provide. However the economic crisis has been hindering such growth.

Average premium paid per insured person was ~250€ per year in 2010. Mainstream insurance companies accept that some ambulatory expenses, which previously demanded the patient to stay over night, to be considered as hospitalization.

Hospitalization, Ambulatory and Dental care are the most contracted coverages.

Main Health Insurance		Coverage			Waiting Period
		Basic	Plus	Premium	
Multicare	• Hospitalization	50,000	50,000	250,000	180 Days
	• Ambulatory	-	2,500	10,000	180 Days
	• Medication	-	-	1,000	60 Days
Medis	• Hospitalization	15,000	50,000	75,000	90 Days
	• Ambulatory	1,000	2,500	5,000	60 Days
	• Medication	-	-	-	-

Fig.14. Coverage an Waiting periods of main health insurance.

Source: www.multicare.com, www.medis.pt

Insurance companies are not obliged to accept all clients – they may practice skimming, selecting lower risk patients. Clients with pre-existing diseases, chronic or infectious diseases, are generally excluded. Direct skimming methods are expensive, thus indirect patient selection methods are used. There is no offer available for higher risk clients.

Conditions:

•Waiting periods

•Fixed co-payments per service;

•Caps;

•Higher premiums when pre-conditions are identified.

Private health insurance has contributions (payments) based on risk of the population that take the contracts offered.

In many circumstances, the health insurance arrangement does require patients to make co-payments. Patients may go to health care providers they freely choose if they are willing to pay at the moment of consumption. Co-payments may differ according to existing agreement between the providers and the payers (health insurance companies).

The out-of-pocket payments constitute another source of funds. Part of it is due to pure demand decisions by patients while the other results from health insurance schemes.

(c 4) Subsystems

ADSE is the largest subsystem with 1,3M beneficiaries and is controlled by the Ministry of Finance. ADSE is financed through employee (1,5% on wages) and employer contributions (2,5%) (ADSE, 2011).

Fig.15. Main subsystems and number of beneficiaries.

Source: ERS, 2009.

Troika (European Central Bank + International Monetary Fund + European Commission) Memorandum of Understanding (MoU) determines that ADSE should be self-sustainable until 2016**.** Cost of ADSE, ADM and SAD are to be reduced 30% in 2012 and 20% in 2013**,** further reductions should be made in subsequent years until attain self-sustainability in 2016**.** The reduction of expenses is to be made by lowering employer's contribution**,** adjusting the scope of health benefits.

The in-network co-payment of ADSE is 100% for oncology, hemodialysis and child-birth and 80% for mostly all of the remainder acts.

In 2011 total expenditure was 559M €. Expenses with medication in ambulatory and hospitalization accounted for 19,4M €, (3,47% of total ADSE expenses) among which 6,2M € correspond to expenditure with antineoplastic (oncology) and immunomodulators (e.g. acute asthma medicines). The costs with oncology were 4,2M € in 2011.

(c 5) Health expenses with medicines

In 2009 the share of pharmaceuticals expenses in total health care expenditure in Portugal was of 21,5% and of 24 % in 2010 (OECD, 2012). For the average of the EU member states it accounted for 19%. Pharmaceutical expenditure was therefore the third biggest cause of the healthcare costs: after inpatient stay and outpatient care.

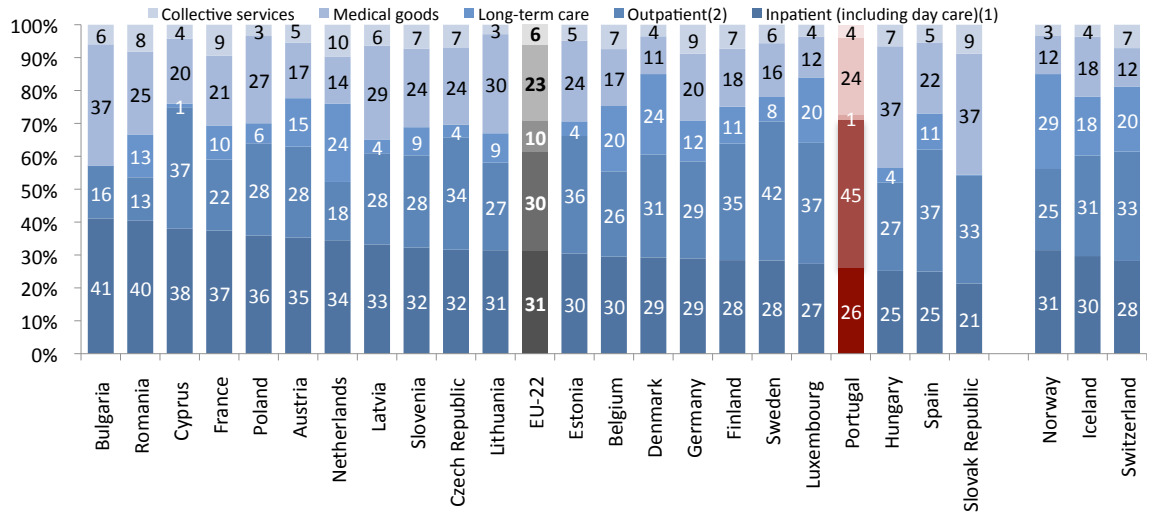

Fig.16. Current health expenditure by function of health care, 2010.

Source: OECD, 2012.

This represented 2% (public + private health expenditures) of Portuguese GDP and it represented 349€ per capita in 2010 (OECD, 2012).

Portuguese healthcare expenses have been said to be of 10,7% of Portuguese GDP in 2010. In relation health expenses with medicines was of 0,95% of GDP for 2009. What represents 18,5% of the NHS budget.

	2005	2006	2007	2008	2009 1)
Orçamento do SNS / *NHS Budget*	7 663	7 835	7 831	8 034	8 407
Encargos do SNS com Medicamentos *NHS Expenditure with Medicines*	1 446	1 423	1 398	1 467	1 559
Encargos do SNS com Medicamentos no Orçamento SNS *NHS Expenditure with Medicines in NHS Budget*	18,9%	18,2%	17,9%	18,3%	18,5%
Encargos do SNS com Medicamentos no PIB *NHS Expenditure in Medicines as a % of GDP*	0,97%	0,92%	0,86%	0,88%	0,95%

Fonte / *Source*: ACSS e INE
1) Valores Provisórios / *Provisory Data*
Unidade | *Unit*: 10^6 EUR

Fig.17. NHS budget, medicine expenses.

Source: Infarmed: ACSS and INE, 2009.

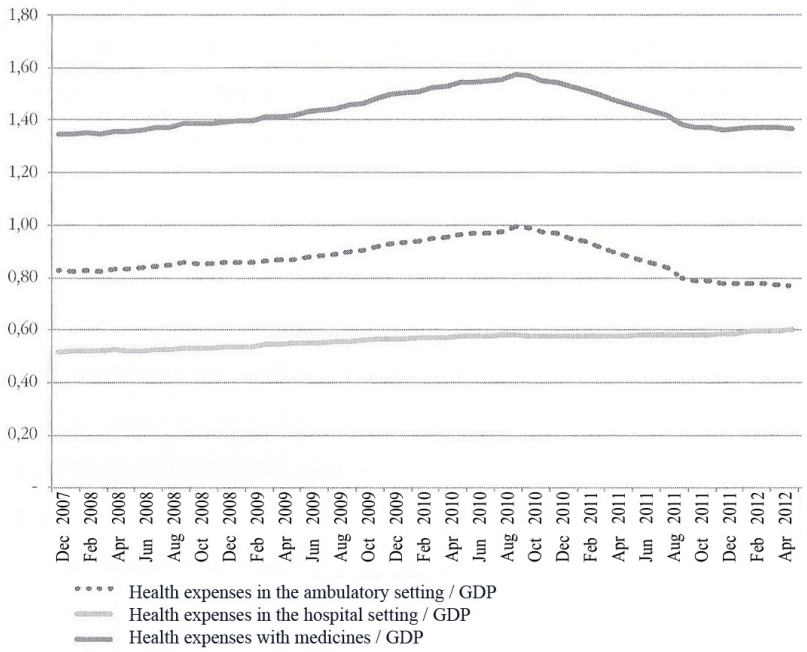

Fig.18. Evolution of the Public Healthcare Expenses Ambulatory, In Hospital and Medicines.

Source: Fernandes, 2012.

From the overall medicine expenses of Portugal in 2009, it cost 68,9% to the NHS, 11,8% to the subsystems with ADSE having the biggest share, 8,4% in 2009. Out of the Counter + Remaining market was 19,4%.

	2005 a)	2006 a)	2007	2008	2009
Mercado do SNS / *NHS Market*	64,5%	63,4%	65,8%	66,7%	68,7%
Mercado dos Subsistemas / *Subsystems Market*	14,3%	13,2%	12,7%	13,5%	11,8%
ADSE + M. Justiça / *ADSE + Ministery of Justice*	8,2%	8,1%	8,4%	8,4%	8,4%
Outros Subsistemas / *Other Subsystems*	6,1%	5,1%	4,3%	5,1%	3,4%
Mercado MNSRM + Restante Mercado *OTC Market + Remaining Market*	21,2%	23,4%	21,5%	19,8%	19,4%
Mercado Total / *Total Market*	100%(a)	100%(a)	100%	100%	100%

Fig.19. Medicines Market Structure.

Source: Infarmed, 2009.

Total number of medicines with no reimbursement in 2009 was 42.441 over the 50.118 total medicines in the market. This value has been increasing from 2005 where the number of non-reimbursed medicines was 27.655.

The value of NHS expenditure with the most expensive medicines (≥ €250) was of 0,3% of total NHS expenditure with medicines.

	2005			2006			2007			2008			2009		
	PVP *RP*	SNS *NHS*	Emb. *Pack*	PVP *RP*	SNS *NHS*	Emb. *Pack*	PVP *RP*	SNS *NHS*	Emb. *Pack*	PVP *RP*	SNS *NHS*	Emb. *Pack*	PVP *RP*	SNS *NHS*	Emb. *Pack*
< €5	4,8%	4,0%	25,1%	4,4%	3,7%	24,0%	4,8%	4,0%	25,3%	4,8%	4,0%	25,1%	4,7%	4,0%	24,7%
€5 - €24,99	38,7%	37,7%	52,6%	37,3%	36,2%	52,6%	39,5%	38,0%	53,3%	39,7%	38,1%	53,6%	39,8%	37,5%	54,1%
€25 - €49,99	40,5%	40,9%	18,6%	38,7%	39,1%	18,6%	34,7%	35,9%	16,0%	35,7%	36,6%	16,3%	32,5%	33,7%	15,5%
€50 - €149,99	15,4%	16,8%	3,6%	18,7%	19,9%	4,7%	20,1%	20,9%	5,3%	18,3%	19,5%	4,9%	21,4%	22,8%	5,6%
€150 - €249,99	0,5%	0,6%	0,0%	0,7%	1,0%	0,1%	0,9%	1,2%	0,1%	1,3%	1,6%	0,1%	1,3%	1,8%	0,1%
≥ €250	0,2%	0,1%	0,0%	0,2%	0,1%	0,0%	0,2%	0,1%	0,0%	0,2%	0,1%	0,0%	0,3%	0,3%	0,0%

Fig.20. Distribution of NHS Sales (RP), NHS expenditure and % of package by price range.

Source: Infarmed, 2009.

The antineoplastic medicines and immunomodalators agents (medicines used in cancer treatment and intestinal infections respectively) account for 0,46% of the total expenses with medicines.

Grupos Farmacoterapêuticos / *Pharmacotherapeutic Groups*	SNS / *NHS*
Aparelho Cardiovascular / *Cardiovascular System*	30,56%
Sistema Nervoso Central / *Central Nervous System*	21,51%
Hormonas e Medicamentos usados no Tratamento das Doenças Endócrinas / *Endocrine system*	10,12%
Aparelho Digestivo / *Digestive System*	9,47%
Aparelho Locomotor / *Locomotor System*	8,70%
Medicamentos Anti-Infecciosos / *Anti-Infectives Products*	5,07%
Sangue / *Blood*	4,70%
Aparelho Respiratório / *Respiratory System*	3,96%
Medicamentos usados em Afecções Oculares / *Drugs for Ophthalmologic Use*	2,02%
Aparelho Geniturinário / *Genitourinary System*	1,75%
Medicamentos Antineoplásicos e Imunomoduladores / *Antineoplastic and Immunomodulators Agents*	0,49%
Medicação Antialérgica / *Antiallergic Medication*	0,44%
Medicamentos usados em Afecções Cutâneas / *Dermatological Agents*	0,43%
Vacinas e Imunoglobulinas / *Vaccines and Immunoglobulins*	0,39%
Medicamentos usados em Afecções Otorrinolaringológicas / *Otological and Oropharyngeal Drugs*	0,23%
Nutrição / *Nutrition*	0,14%
Medicamentos usados no Tratamento de Intoxicações / *Anti-Poisoning Agents*	0,01%
Correctivos da Volémia e das Alterações Electrolíticas / *Electrolytic and Fluid Balance Regulation Agents*	0,01%

Fig.21. NHS Expenditure Distribution by Pharmacotherapeutic Groups.

Source: Infarmed, 2009.

The top substance that had in 2009 the highest number of packages sold was the paracetamol with around 3,6M €. But the top active substance with highest expenditure was the Omeprazol representing about 60,5M € for 2M packages sold. Olanzapina the 4th largest costs 22 M € but has only 0,29M packages sold.

In terms of pharmaceutical companies and what they represent to the NHS cost AstraZeneca is the highest with around 94M €.

(c 6) Are innovative medicines being used by public NHS

Over the past years an intense discussion has occurred over the prescription restrictions and controlled hospitals drug formulary, the discussion has been intensified once Troika entered in Portugal.

The MoU established measures over the necessity of reducing public health expenditure with medicines: reduction of 1,25% of GDP until the end 2012 and about 1% of GDP in 2013 (in line with the EU average). This implies a reduction of 841.857M € until the end of 2012 on the public expenses with medicines, what means about 46,8 M € per month (Costa, et al., 2011),

The health minister asked to Conselho Nacional de Ética para as Ciências da Vida - CNECV for a study about the ethical financing of the very costly medicines for Oncology, HIV AIDS and rheumatoid arthritis. Those medicines expenses represented in 2011 a health expense of 513M €.

International Nonproprietary Names	2009	2010	2011	Jan-July 2012
Oncologic	211.864.700	223.016.442	222.236.802	125.268.473
HIV AIDS	172.398.376	190.124.448	224.624.956	136.194.693
Rheumatoid Arthritis	43.524.415	55.739.452	66.744.937	44.858.383
Total	**427.787.491**	**468.880.342**	**513.606.695**	**306.321.549**

Fig.22. Yearly expenses with medicines

Source: Infarmed, 2012.

In the US, during the 2010 decade, the total expense with subsidies for cancer drugs has risen from $65M to more than $500M. The cancer researcher Dr Karikios from the University of Sydney, said: "We are seeing some drugs approved that extend median survival by only a few months, yet they add hundreds of millions of dollars to health system costs," "many are asking whether that money could be better spent" (**Forbes, 2010).**

Rationalization of medicines is one of the top concerns of the NHS. The report of CNECV suggests that the NHS should move from an *implicit rationalization,* what has been happening; to an *explicit and transparent rationalization*. CNECV also considers that ethical fundaments exists to promote the cost containment with medicines in the NHS. Those measures should at the same time guarantee the equal distribution of resources. Two visions exist: to give the *major good for major number of people* (Rawls, 1971) and what is considered more realistic view: the major possible good for the major number of people. The CNECV proposes a criteria of choice for two comparable medicines (comparable effectiveness) the *cheapest from the bests* and not the *best of the cheapest.*

The primary goal of any healthcare policy should be to maximize the health of the population within the limits of the available resources (Lieven, 2010).

3. Method

Methods of research and analysis that were employed:

•Health sector in context

•Study of the literature

•Stakeholders interviews

•Hypothesis matrix that assesses the private market from relevant angles for innovative medicines

•Assess fit of innovative medicines portfolio with providers offer and financing models, identification of opportunities

•Evaluate trends within the health care industry with scholars and major players

•Recommendations

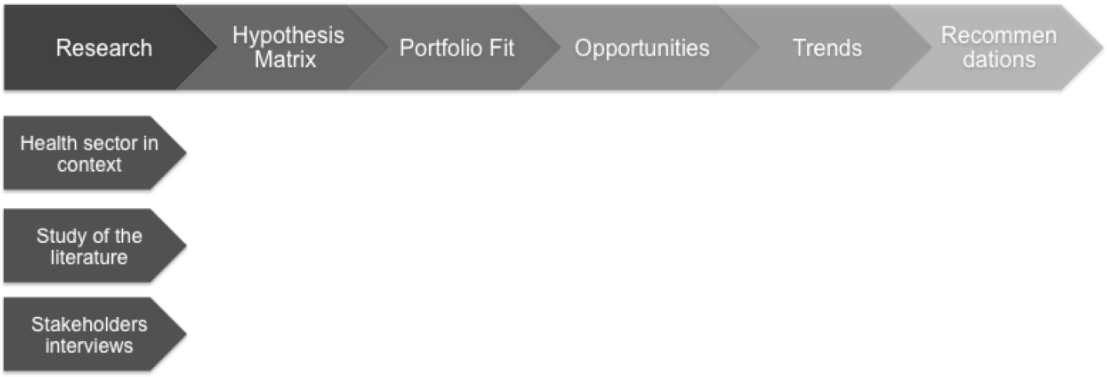

Fig.23. Methodology for the Work Project

Primary data: interviews with some of the major relevant players of the health system.

INSTITUTION	ROLE	INTERVIEWEE
Universidade Católica	Professor	Miguel Gouveia
	Observatory of PPP's	Ricardo Reis
PPP Loures (ESS)	Administrator of PPP Loures	Artur Vaz
Hospital da Luz (ESS)	Administrator of Hospital da Luz	Pedro Líbano Monteiro
José Mello Saúde	Administrator	Lopes Martins
	Director Strategic Planning	Sofia Araújo Fernandes
Multicare	Administrator	Carlos Coutinho
	Marketing Director	Maria Jesus Fernandes
ADSE	General Director	Luís Pires
Entidade Reguladora da Saúde	President	Jorge Simões
Parliament	Former Health Minister	Maria de Belém Roseira

Fig.24. Interviewees list

Fig.25. Interviews cross areas

Secondary data: data research from entities like OCDE, Infarmed, INE, APHP, ERS, CEIS and others; and existent literature about the topic – see references list.

4. Results

Public sector

1. High pressure for cost reduction in hospitals, impairing service by lack of resources.
2. Infarmed delaying approval on reimbursement of new indications as means to control total costs in NHS.
3. Troika promotes rationalization of medicine expenses.
4. The public hospitals of NHS may go from implicit rationalization to explicit rationalization as per CNECV document.

Private sector

1. Main players growing by consolidation.
2. Strong reliance on insurance and sub-systems for financing.
3. Size of financing organisations client pool is crucial to secure competitive margins with in network providers and affordable pricing to patients.
4. Insurance companies shifting coverage of ambulatory to hospitalisation.
5. Insurance companies increasing caps values of coverage plan in hospitalization to cover illnesses with very expensive treatments like cancer treatments and cardiac surgeries.
6. Increase in coverage caps and increase in client payment of the insurance plan are not proportional once the probability (risk) of having a very expensive treatment is very low when compares for instance with the number of consultations per year (what is more certain).

Private providers – implications for pharmaceutical companies

•Private health sector is concentrated in four 4 major players. Addressing them would cover 70% of the market.

•However private Ophtha small clinics have high market share, representing the main segment to be addressed by pharmaceutical companies for ophthalmologic products.

•Major private players provide services on some therapeutics which fit innovative pharmaceuticals portfolio, having agreements with major insurance companies and health subsystems.

•Hospital's specialty doctors endorse the medication, but the allocation of funds is made by Therapeutics Committee.

•Procurement for each group is centralized, handling negotiations with pharmaceuticals by portfolio.

Financing – implications for pharmaceutical companies

•Private health sector is financed by health care subsystems, private insurance, and out of pocket patients.

•Spending in private is increasing in comparison to public.

•ADSE covers 80% of most therapies and 100% for oncology, including medication not reimbursed by NHS.

•Mainstream insurance packages also cover oncology, but with caps that can limit treatment.

•Pre-existing conditions such as diabetes or asthma limit the probabilities of getting health insurance or constrain coverage.

•Relevance of subsystems increases dramatically in catastrophic diseases once they do totally reimburse the treatment contrary to private health insurances.

•Rare diseases although they might have very costly innovative medicines to threat them as they are rare the risk could be spread out throughout the beneficiaries pool without much weight in terms of payment.

•The use of the innovative medicines by the private players can attract more clients by covering those diseases on their health plans.

Main Private Groups	Main Hospitals	Services - Specialty doctors and resources to treat diseases				Financing		
		Specialty G	Specialty H	Specialty I	Specialty J	Health Insurance	Subsystems	Out of Pocket
José de Mello Saúde	• CUF Infante Santo	✔	✔	✔	✔	74-69%	10-15% ADSE, SAMS, PT ACS	16%
	• CUF Descobertas	✔	✔	✔	✔			
	• CUF Porto	✔	✔	✔	✔			
Hospitais Privados de Portugal	• Lusíadas	✔	✔	✔	✔	✔ % Not known	✔ ADSE, PT ACS, SAMS, ADM % Not known	✔ % Not known
	• Boavista	✔	✔	✔	✔			
Espírito Santo Saúde	• Hospital da Luz	✔	✔	✔	✔	55%	30% [1] ADSE, PT ACS, SAMS, ADM	15%
Trofa Saúde		✔	✔	✔	✔	✔ % Not known	✔ % Not known	✔ % Not known
Small Clinics		Not relevant	Not relevant	Not relevant	✔	Variable	Variable	Variable

[1] Relative weight of sub-systems increases for some catastrophic illnesses: example - Oncology Department in Hospital da Luz

Fig.26. Services and financing distribution of main groups.

Source: Interviews.

One of the specialty considered is not so concentrated on the private four major groups, their market share is spread in smaller clinics.

The portfolio fit can be measured by indication considering the pool of patients with the disease, and if they're approved or not for reimbursement by the Infarmed. The funding should be accessed to verify if the patients can have this expensive medicines reimbursed, either if they are

ADSE beneficiaries or have a voluntary health insurance (VHI). Of course the disease can only be treated privately if the private providers have the means (human capital, equipment and infrastructures) to threat it. The four major players were analysed: JMS, ESS, HHP and Trofa.

Fig.27. Portfolio fit

The same product can be indicated for the treatment of several diseases.

Pharmaceutical companies estimate the size of target Pool of Patients based on epidemiological data.

Products can be prescribed even if not approved for reimbursement by Infarmed, but the probability of capturing patients is very low once these innovative medicines are all very costly not less tan 2.000 a year, not more than 50.000 a year.

Financing:

ADSE Reimburse 80%

ADSE Reimburse 100%

Voluntary Health Insurances cover but has co-payment values

Voluntary Health Insurances doesn't cover patients with pre-existing conditions/diseases

Not reimbursed by Voluntary Health Insurances once it is not approved for reimbursement by Infarmed

Almost no fit for out of pocket, due to the high cost of medicines

Private Providers:

Private specialists and resources able to give treatment to the disease

Private specialists and resources NOT able to give treatment to the disease

Analysis of the Portfolio Fit:

Indications R and S have no fit once they're not treated by the private sector, not possible technically and financially not attractive, due to the fact that only the public health system has the scale to maintain its attractiveness.

Indication Q has all the patients already captured, therefore there is no fit for an increase in sales.

Indication W and O have 100% fit for ADSE beneficiaries but very low fit for VHI (it's usually a pre-existing condition when a health insurance plan is signed).

Indication X and Y has lower fit for ADSE (80% reimbursement) and the pool of patients to capture is the highest of all. Almost no fit for VHI.

Indication K, M and Z as they are not reimbursed by Infarmed they have only fit for ADSE beneficiaries (100% reimbursement – Indication K and M; 80% reimbursement - Indication Z)

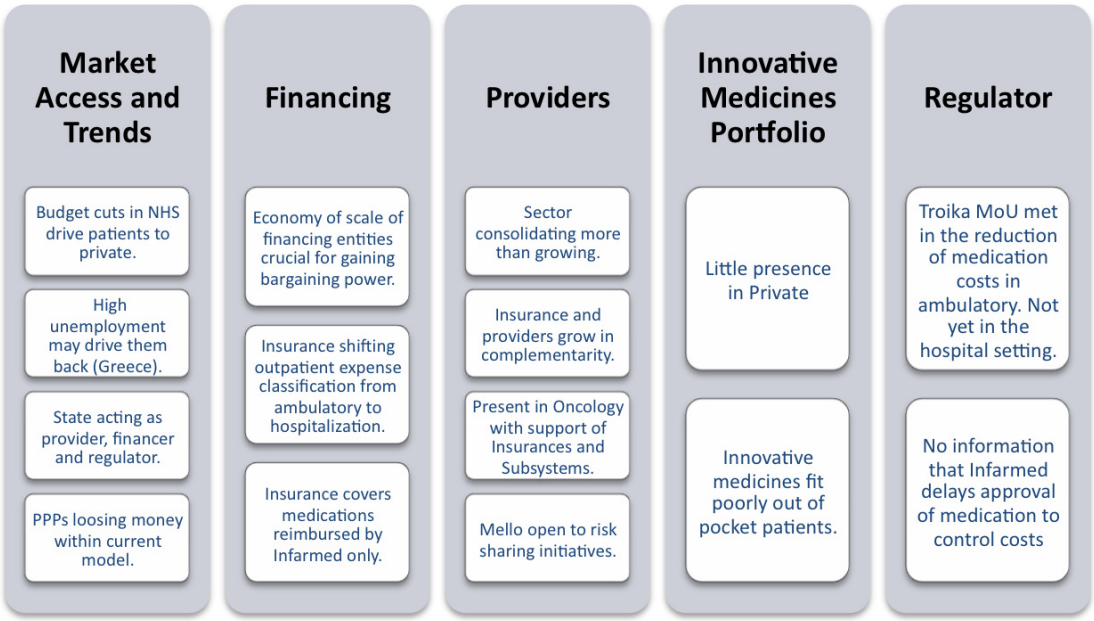

Fig.28. Actual situation in Portuguese healthcare

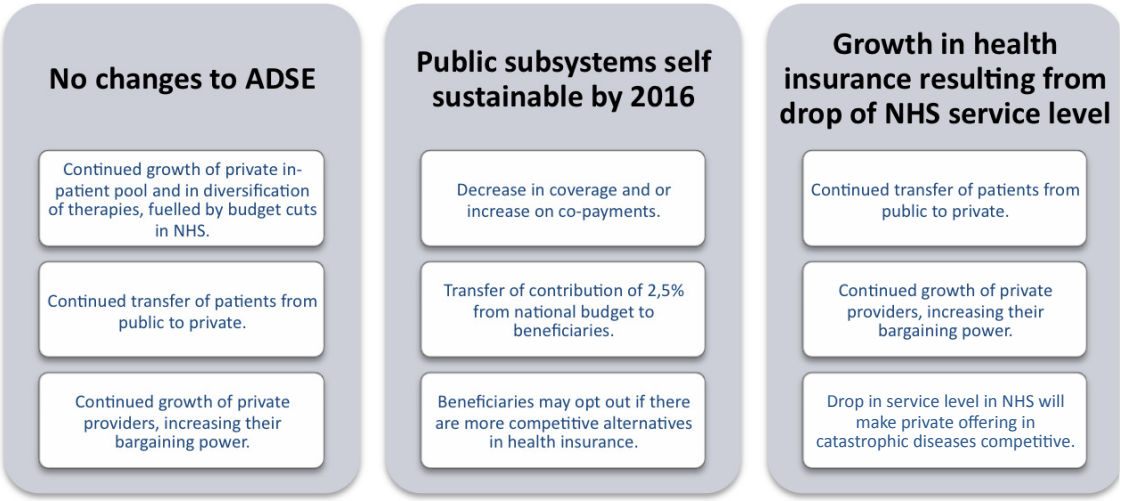

Fig.29. Possible trends in Portuguese healthcare sector

5. Conclusions

Presentation of conclusions and implications

Within the portuguese health context, can the private health sector absorb the uncaptured pool of patients in need for innovative medicines?

Private providers ability to absorb the uncaptured pool of patients in need for innovative medicines depends on financing models.

Recommendations

1. Make the most use of subsystems, a nearly uncapped financing model, more importantly even for non-reimbursed medications in public.

3. Generate incentives to private insurances to cope with innovative medicines not yet approved for reimbursement as a way of differentiation and complementarity to the NHS.

4. Share efficiency cost studies with private players to allow them to know the cutting expenses, for instance in terms of the duration of inpatient stay.

2. Provide support in co-payments for ADSE patients, in the case of 80% reimbursement, trough third parties.

3. In the case of medicines with several annual doses ensure care giving patients with a bundle offering that provides adequate first dose and maintenance therapy.

4. Promote non-explored private market for oncology products in major providers.

5. Educate patients about the best therapies of the market – transparency.

6. Some diseases are not treated in private due to technical and financial reasons.

a-The treatment of the disease requires, moreover than a specific innovative medicine, specialized resources and infrastructure;

b-It is a rare disease therefore it's not profitable to have the specific resources (medical doctors and nurses or equipment).

7. Incentives to private providers like insurances: agreements could be based in success fees based effectiveness.

Assist in co-payment:

•Support subsystem co-payment cash back via third party.

•Patients submit (partial) reimbursement request to third party.

•Third parties can be patients associations by disease.

•The pharmaceutical company may distribute money to the associations of patient.

•Third party required due to the prohibited contact between pharmaceutical companies and its patients.

The alignment of the private industry players: private providers and private insurances with pharmaceuticals that develop innovative medicines can improve the value creation for the three players. Private providers and insurances by differentiating them from the rationalized NHS and from other private players they would attract more clients to their services. Pharmaceutical companies of innovative medicines would generate value for higher sales of these medicines. Covering the patient pool of patients not covered.

Discussion of main limitations of study

After defining this global strategy on how to tackle the private sector, and what are the specificities of each players and the respective trends, a indication by indication analysis should be done.

As this is a holistic strategic overview of the problem, some difficulties could arise during the implementation of a recommendation. To minimize that risk interviews could be done now not to management level of the hospitals but to doctors that prescribes innovative medicines.

6. Self-evaluation

With the process of the work project what I retain the most is the immersion process were I was able to acquire an immense knowledge of the healthcare sector in Portugal.

I do also retain that the most important aspect to define a strategy for any sector is to hear in person their players concerns. Detecting the problem is much more than half the way for arriving to a solution.

Lastly I would like to comment that this project was what enabled me to start working on a consulting company on the healthcare area and for that I'm very grateful.

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8. Appendices

Players of the Portuguese Health System

The system is constituted by public and private providers, and is financed by the state, by the subsystems, by private health insurances or by out of pocket payments (OOP). The providers are composed by the primary centers, the hospitals, long term care, Meios Complementares de Diagnóstico e Terapêutica (MCDT) clinics and pharmacies, and they're supplied in pharmaceutics and medical products and equipment.

The states legislates the healthcare system trough the Ministry of Health, Ministry of Economy and Ministry of Finance. The regulators are the Entidade Reguladora da Saúde (ERS), Direcção Geral da Saúde (DGS), Administração Central do Sistema de Saúde (ACSS).

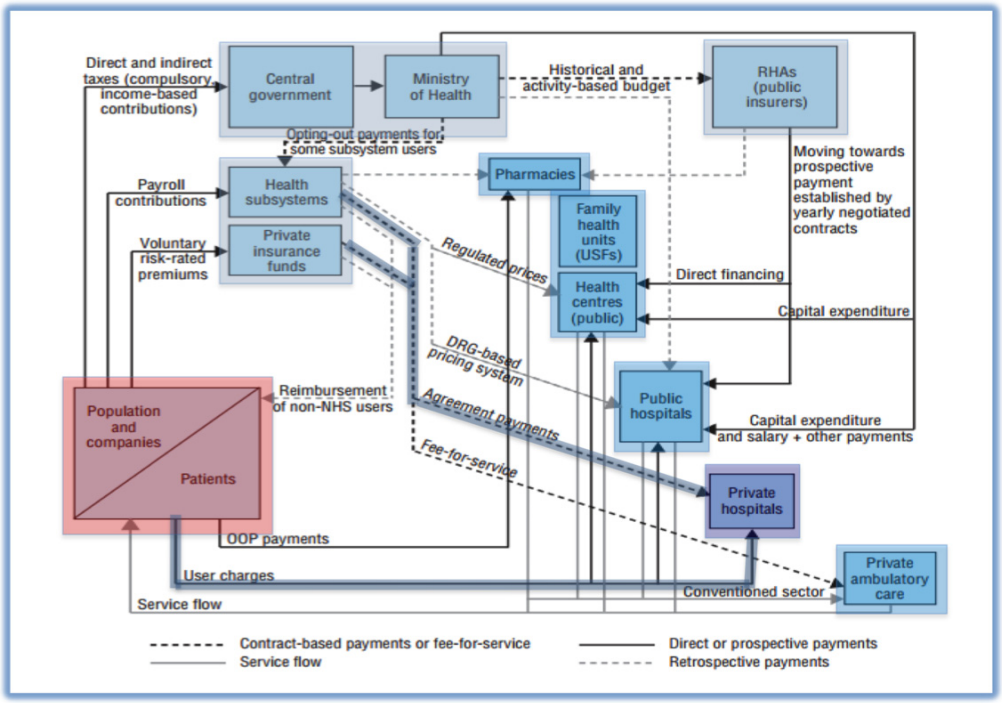

Fig.30. Portuguese healthcare system: public and private financing flows.

Source: Portugal – Health System Review, 2011.

Infarmed Cost Tables

International Nonproprietary Names	2009	2010	2011	Jan-July 2012
Abacavir	1.479.186	1.518.680	1.706.149	1.075.309
Abacavir + Lamivudina	7.541.709	9.653.943	15.971.302	11.219.569
Abacavir + Lamivudina + Zidovudina	1.998.317	1.758.033	1.524.557	662.720
Atazanavir	14.260.928	18.218.506	22.172.630	12.824.266
Darunavir	3.198.631	5.602.737	12.189.032	10.003.288
Didanosina	1.785.676	1.243.662	870.106	367.142
Efavirenz	18.266.545	14.115.392	13.586.927	7.448.043
Efavirenz + Emtricitabina + Tenofovir	9.096.510	22.767.530	33.328.517	22.166.252
Emtricitabina	396.228	288.435	228.165	114.474
Emtricitabina + Tenofovir	38.169.302	42.018.697	50.744.852	31.974.231
Enfuvirtida	534.563	217.204	107.522	62.498
Estavudina	1.246.128	839.397	546.261	206.390
Etravirina	93.616	695.920	1.510.288	1.277.873
Fosamprenavir	1.600.573	1.389.118	1.501.330	695.351
Indinavir	670.350	452.576	261.075	109.763
Lamivudina	4.363.474	3.263.107	2.429.032	728.865
Lamivudina + Zidovudina	15.165.553	12.174.174	8.593.516	3.054.835
Lopinavir + Ritonavir	24.573.833	23.199.354	21.733.556	11.587.897
Maraviroc	270.868	673.850	972.686	581.465
Nelfinavir	68.579	54.161	42.846	20.825
Nevirapina	4.557.202	4.940.112	5.792.725	1.550.549
Raltegravir	4.736.432	7.399.034	10.550.066	7.909.741
Ritonavir	2.044.311	2.240.497	2.897.441	1.842.829
Saquinavir	4.036.354	3.472.779	3.050.833	1.462.776
Tenofovir	9.768.425	9.936.569	10.777.326	6.593.600
Tipranavir	478.096	379.338	315.034	187.578
Zidovudina	1.996.988	1.611.643	1.221.186	466.563
Total	**172.398.376**	**190.124.448**	**224.624.956**	**136.194.693**

Fig.31. Yearly expenses with HIV AIDS.

Source: Infarmed, 2012

International Nonproprietary Names	2009	2010	2011	Jan-July 2012
Abatacept	43.020	190.342	306.474	132.403
Adalimumab	10.214.829	17.138.859	21.742.967	14.244.894
Anacinra	385.711	286.728	276.759	152.108
Etanercept	18.055.561	20.830.643	21.900.830	13.902.640
Golimumab			1.076.412	1.651.023
Infliximab	14.822.254	17.228.867	18.376.436	11.325.959
Tocilizumab	3.040	64.014	963.938	922.667
Ustecinumab			2.101.121	2.526.689
Total	**43.524.415**	**55.739.452**	**66.744.937**	**44.858.383**

Fig.32. Yearly expenses with Biological Medicines for the treatment of Rheumatoid Arthritis.

Source: Infarmed, 2012.

International Nonproprietary Names	2009	2010	2011	Jan-July 2012
Abiraterona			58.841	991.323
Ácido 5-aminolevulínico		29.998	21.815	15.635
Aldesleucina			6.067	
Alemtuzumab	140.139	215.523	313.366	325.955
Aminolevulinato de metilo	26.082	38.199	50.082	24.007
Amsacrina	9.043	4.377	7.703	8.161
Anastrozol	3.801.936	2.543.088	1.721.656	735.685
Asparaginase	201.060	166.656	145.923	76.961
Azacitidina	1.263.358	1.780.285	2.295.869	1.737.947
Bacilo Calmette-Guérin	499.213	530.092	551.751	340.768
Bendamustina				2.048
Bevacizumab	12.120.676	12.591.086	12.119.082	7.133.604
Bexaroteno	456.859	413.503	507.973	230.985
Bicalutamida	4.554.945	2.448.207	1.520.757	641.724
Bleomicina	93.149	94.514	99.294	59.772
Bortezomib	5.195.215	5.184.955	6.759.010	4.478.900
Buserrelina	72.658	52.382	34.965	13.310
Bussulfano	310.771	359.785	328.321	204.870
Cabazitaxel			112.823	208.051
Capecitabina	5.562.519	5.835.467	6.819.681	3.441.900
Carboplatina	475.006	428.536	408.158	253.713
Carmustina	192.997	281.320	78.680	24.578
Cetuximab	7.726.039	11.500.781	12.391.619	6.557.150
Ciclofosfamida	375.854	461.090	479.049	279.920
Ciproterona	917.609	767.521	714.243	306.842
Cisplatina	244.911	269.695	290.852	147.481
Citarabina	326.741	313.309	278.974	165.489
Cladribina	154.904	131.542	120.069	56.780
Clofarabina	111.628	145.337	450.366	246.334
Clorambucilo	4.346	3.823	3.631	2.983
Clorometina	54.430	2.402	24	
Crisantaspase	124.421	154.045	188.211	248.843
Dacarbazina	173.119	194.389	213.620	109.649
Dactinomicina	14.090	25.488	14.689	14.256
Dasatinib	2.587.264	3.125.522	3.961.303	2.730.327
Daunorrubicina	32.674	39.617	47.825	25.967
Degarrelix			17.441	33.196
Diftitox denileucina		80.136	26.712	
Docetaxel	20.271.623	14.333.167	7.103.265	1.276.711
Doxorrubicina	3.748.998	3.943.661	3.542.793	873.566
Epirrubicina	728.327	434.013	343.638	156.318
Eribulina			10.600	69.112
Erlotinib	5.420.879	6.700.898	7.888.558	4.802.090
Estramustina	265.947	206.134	192.058	98.746
Etoposido	157.334	303.937	349.812	170.241
Everolímus		32.255	375.157	422.118
Exemestano	1.718.394	1.696.306	963.155	156.106
Fludarabina	519.480	439.012	353.552	129.401
Fluorouracilo	536.958	516.002	495.614	287.488
Flutamida	38.550	22.927	17.176	9.301
Fotemustina	54.244	66.538	110.766	55.228
Fulvestrant	920.880	1.520.279	2.422.778	1.421.088
Gefitinib		74.320	465.853	309.294
Gemcitabina	2.528.637	1.244.085	787.274	391.906
Gemtuzumab ozogamicina	9.352	3.741		
Gonadorrelina	22.797	20.668	14.495	9.778
Goserrelina	6.161.377	5.808.389	5.370.495	2.999.782
Hidroxicarbamida	529.094	546.934	585.592	363.942
Ibritumomab tiuxetano	157.500	84.100	42.300	11.201
Idarrubicina	432.883	489.343	376.900	200.311
Ifosfamida	293.863	432.917	368.963	207.240
Imatinib	21.500.573	22.579.609	25.241.624	15.564.319
Interferão alfa-2a	227.539	182.760	144.883	91.131

Interferão alfa-2b	185.907	162.722	207.730	121.968
Interferão gama-1b	75.504	73.722	61.994	29.511
Ipilimumab				90.100
Irinotecano	2.272.291	1.914.611	1.239.157	469.203
Lapatinib	494.959	852.108	1.266.654	990.872
Lenalidomida	3.288.790	5.159.816	4.960.534	3.701.687
Letrozol	1.802.759	1.492.787	539.248	186.986
Leuprorrelina	4.230.949	4.682.305	5.302.359	3.173.863
Lomustina	53.711	38.599	24.695	15.353
Medroxiprogesterona	375	369	431	279
Megestrol	462.115	550.752	450.691	233.283
Melfalano	78.090	74.116	81.170	64.916
Mercaptopurina	89.625	88.610	89.960	79.245
Metirapona	17.629	21.502	33.555	15.855
Metotrexato	396.850	396.377	365.418	226.968
Miltefosina	26.880	92.948	97.818	69.223
Mitomicina	821.977	828.697	831.806	465.030
Mitotano	178.682	96.341	194.447	105.024
Mitoxantrona	62.235	62.707	57.050	30.993
Nelarabina	12.164		23.833	49.177
Nilotinib	205.133	233.052	438.253	417.188
Nilutamida	863.760	770.497	808.174	355.819
Nimotuzumab			3.854	
Ofatumumab				23.701
Oxaliplatina	778.010	651.807	507.829	231.470
Paclitaxel	519.623	418.067	425.531	289.925
Panitumumab	20.960	369.947	730.303	477.182
Pazopanib			201.528	232.456
Pegaspargase	204.314	300.070	451.952	217.989
Pemetrexedo	5.388.325	6.295.747	7.404.818	4.400.661
Pentostatina	28.216	19.595	37.957	35.672
Plerixafor	38.648	346.422	339.168	159.228
Porfímero sódico	2.560	2.560		
Procarbazina	218.657	199.156	174.490	79.295
Raltitrexedo	22.455	22.470	16.343	2.856
Rituximab	18.005.556	21.181.648	20.691.853	11.590.812
Sorafenib	2.249.403	3.594.208	3.762.867	1.611.354
Sunitinib	4.734.697	4.965.339	5.182.120	2.973.652
Talidomida	2.235.507	2.325.532	2.355.169	1.347.730
Tamoxifeno	275.524	270.866	273.609	157.135
Tasonermina	54.863	84.933	47.811	52.868
Tegafur + Uramustina	345.037	367.503	249.549	149.233
Temozolomida	4.420.943	4.432.888	2.211.446	935.149
Temsirolímus	164.598	256.732	585.660	364.140
Teniposido	1.164	3.957	2.126	506
Tioguanina	11.465	7.936	8.696	5.827
Tiotepa	25.097	13.837	52.415	85.348
Topotecano	1.181.020	966.000	541.219	202.487
Toremifeno	13.371	6.822	4.259	763
Trabectedina	223.705	925.241	1.274.685	608.401
Trastuzumab	32.618.828	37.421.090	39.110.698	21.824.696
Tretinoína	350.351	355.152	330.057	184.327
Trióxido de arsénio	188.563	159.415	98.637	40.212
Triptorrelina	4.696.591	4.577.019	4.586.957	2.591.218
Trofosfamida			953	699
Verteporfina	421.457	402.276	406.422	262.587
Vinblastina	35.473	38.563	35.320	20.024
Vincristina	66.379	73.033	73.767	41.182
Vindesina	6.340	3.042	4.540	1.606
Vinflunina		40.909	72.737	
Vinorrelbina	2.627.732	2.429.363	2.162.598	1.222.007
Vorinostate			14.142	
Total	**211.864.700**	**223.016.442**	**222.236.802**	**125.268.473**

Fig.33. Yearly expenses with medicines for Oncologic disorders.

Source: Infarmed, 2012.

Important Concepts

IMI: *joint effort of the European Union and pharmaceutical industry in order to boost investments in bio-pharmaceutical research and to overcome bottlenecks in the development of innovative medicines* (IMI JU Factsheet).

EMA: European Marketing Authorizations is a centralized approval for new medical products. It requires acceptance in all EU member states.

Off label: (unlabelled or unapproved) prescription of a medicine is the prescription of a registered medicine for a use that is not included in the product information. The practice is common, with rates up to 40% in adults and up to 90% in pediatric patients. Clinical, safety and ethical issues may arise (Gazarian, et al., 2006).

Rare diseases: A rare disease is a disease with a very low prevalence. In the EU, rare diseases are defined as life-threatening or chronically debilitating diseases that have a prevalence of 50 per 100.000 individuals. There are currently 5.000 to 7.000 rare diseases. Drugs for theses diseases are less likely to be developed by the industry since the market is small and R&D costs are usually too high to make the products profitable.

Products and Companies with top medicines expenditures

When people talk about expensive drugs, they usually are referring to drugs like Lipitor for high cholesterol ($1,500 a year), Zyprexa for schizophrenia ($7,000 a year) or Avastin for cancer ($50,000 a year). But none of these medicines come close to making Forbes' exclusive survey of the most expensive medicines on the planet. The nine drugs on our list all cost more than $200,000 a year for the average patient who takes them. Most of them treat rare genetic diseases that afflict fewer than 10,000 patients. For these diseases, there are few if any other treatments. So biotech companies can charge pretty much whatever they want. Alexion Pharmaceutical's Soliris, at $409,500 a year, is the world's single most expensive drug. In the inverted world of drug pricing, the fewer patients a drug helps, the more it costs. Amazingly, many brutally expensive cancer drugs don't make the cut. Targeted cancer drugs only help a small minority of patients for a few months. This reduces their average cost. Selling drugs for rare diseases has become immensely profitable. There are so few patients that companies don't have to invest as heavily in marketing. Specialty drugs have gotten more expensive than anyone imagined. For years drug companies ignored any disease that didn't afflict millions of patients.

Source: http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases.html

Posição/ *Ranking*	Titular de AIM / *MA Holder*	PVP / *RP*	%	SNS / *NHS*	%	Embalagens / *Packages*	%
1	AstraZeneca	144 128 047	6,31%	93 705 959	6,01%	3 919 707	2,85%
2	Sanofi Pharma BMS	94 571 581	4,14%	70 590 457	4,53%	2 535 103	1,84%
3	Laboratórios Pfizer	113 268 593	4,96%	67 616 040	4,34%	5 040 392	3,67%
4	Merck Sharp & Dohme Limited	63 457 386	2,78%	56 663 483	3,63%	1 404 251	1,02%
5	Merck Sharp & Dohme	75 030 885	3,29%	51 332 947	3,29%	2 969 663	2,16%
6	Sanofi-Aventis	80 192 952	3,51%	50 300 517	3,23%	7 604 766	5,53%
7	Novartis Farma	70 625 464	3,09%	49 334 096	3,16%	3 642 586	2,65%
8	Servier	74 796 293	3,28%	43 257 388	2,77%	5 353 726	3,89%
9	Eli Lilly Nederland	42 582 360	1,87%	39 226 076	2,52%	679 052	0,49%
10	Generis Farmacêutica	43 982 773	1,93%	34 855 306	2,24%	3 305 282	2,40%

Fig.34. Top MA holders with the highest expenditure in the NHS.

Source: Infarmed, 2009.

R&D expenditures

The pharmaceutical industry spends more on R&D than any other industry. The majority of the studied substances do not lead to new medicines, on average there is only 1 in 10.000 probability of a researched substance to lead to a new medicine (Nefarma, 2011).

In 2010 the biotechnology and pharmaceutical industry had a 19,2% share of the invested capital in worldwide R&D, this represents 15,9% of its revenues invested in new medicines, when the majority of the other industries invest only 5% of its turnover in R&D (Nefarma, 2011).

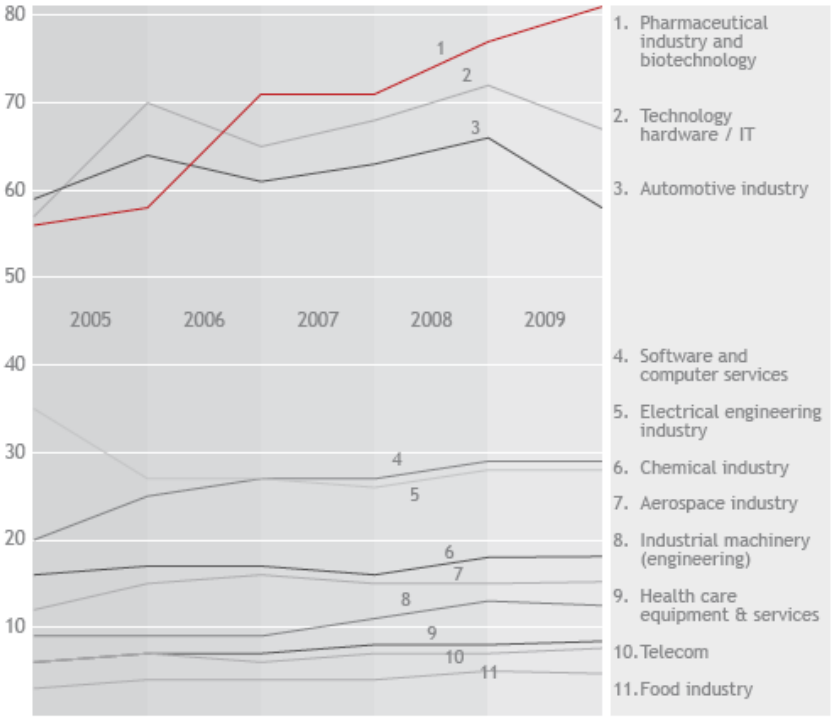

Fig.35. Worldwide expenditure on R&D per sector over the years (B €) and in percentage.

Source: Nefarma, 2011: European Comission, EU Industrial Investment Scoreboard 2010.

Innovation requires ever increasing investments. The international spending on R&D by Americn pharmaceutical companies has steadily increased from 2B $ in 1980 to nearly 48B $ in recent years. In Europe, pharmaceutical companies spent between 7 and 8B € on R&D in the early 1990s and this rose to almost 27 B € in 2009.

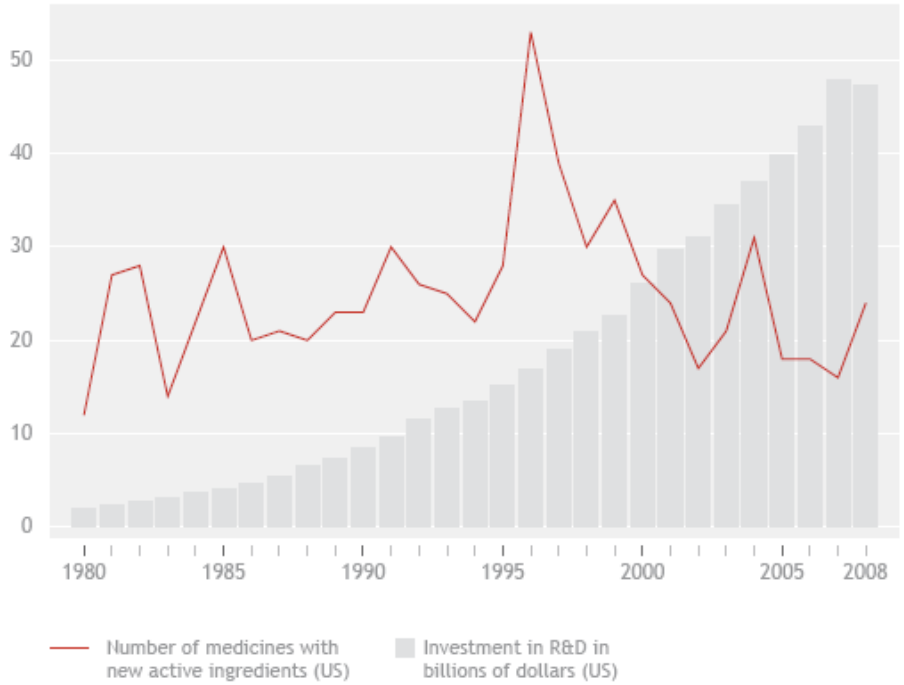

Fig.36. FDA- approved medicines containing a new active compound, versus R&D investment (1980-2008).
Source: Nefarma: DiMAsi, Center for study of drug development, FDA PhRMA.

As per the American Food and Drug Administration (FDA) over the last 50 years, there has been an increasing trend in the number of registrations of medicines with new active compounds.

Marketing Authorizations

Year	MA Applications	Granted Authorizations	% Granted
2005	678	580	85,55%
2006	778	488	62,72%
2007	941	623	66,21%
2008	1170	773	66,07%
2009	924	853	92,32%

Fig.37. MA applications, Granted Authorizations.

Source: Infarmed, 2009.

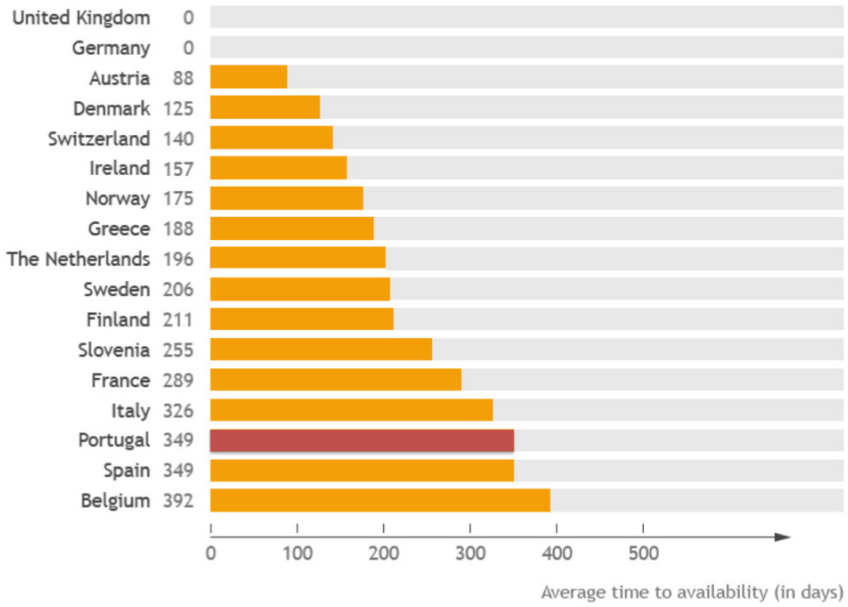

Fig.38. The average time that elapses between commercial licensing of a medicine and its availability to patients.

Source: Nefarma, 2011: Efpia, Patients W.A.I.T Indicator, 2010.

Before patients have access to the latest medicines time is lost with the procedures for reimbursement. In Portugal the W.A.I.T. indicator (waiting to access innovative therapies) in 2010 was of 349 days.